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(54) **SYSTEMS AND METHODS FOR TESTING INTRAOCULAR LENSES**

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(58) **Field of Classification Search** 356/124–127; 351/210–213, 205, 206; 623/6.13, 6.22, 623/6.37, 6.34, 6.43, 6.44
See application file for complete search history.

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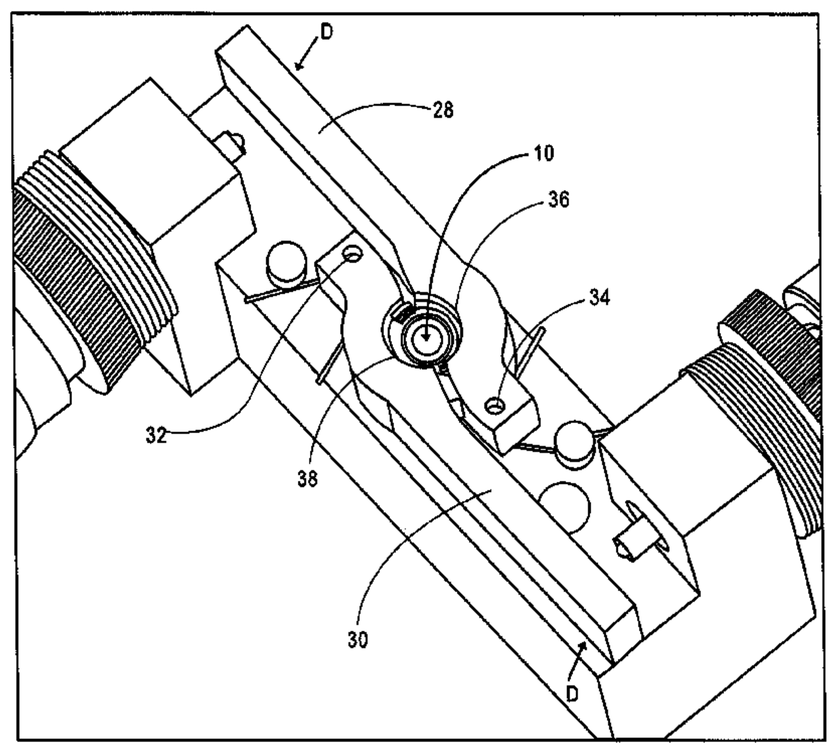
(57) **ABSTRACT**

Systems and their methods of use for testing intraocular lenses outside of the lens capsule. In some embodiments the systems measure an accommodative response based on a force applied to the intraocular lens.

21 Claims, 9 Drawing Sheets



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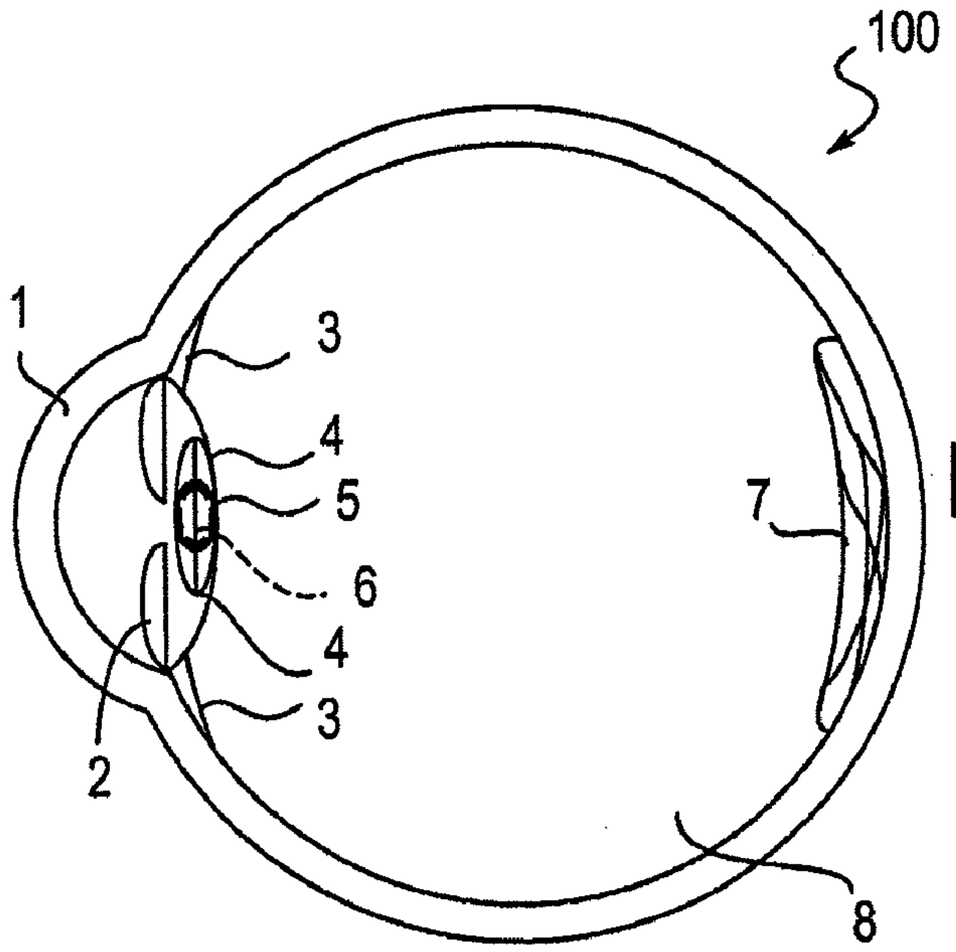

FIG. 1

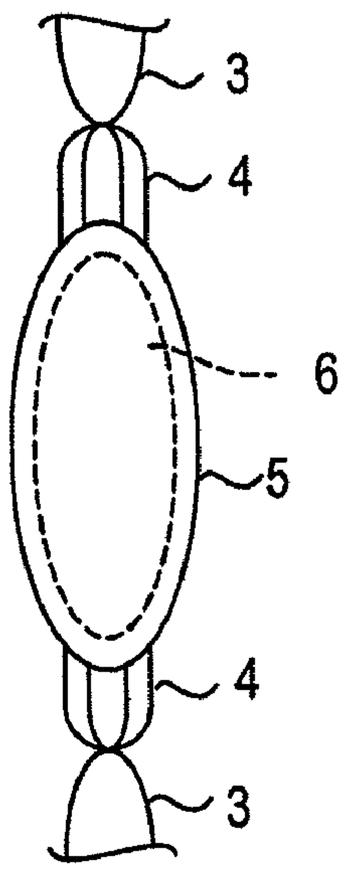

FIG. 2A

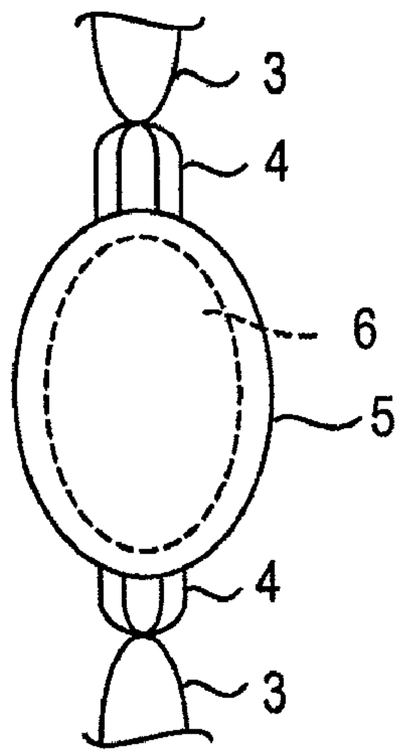

FIG. 2B

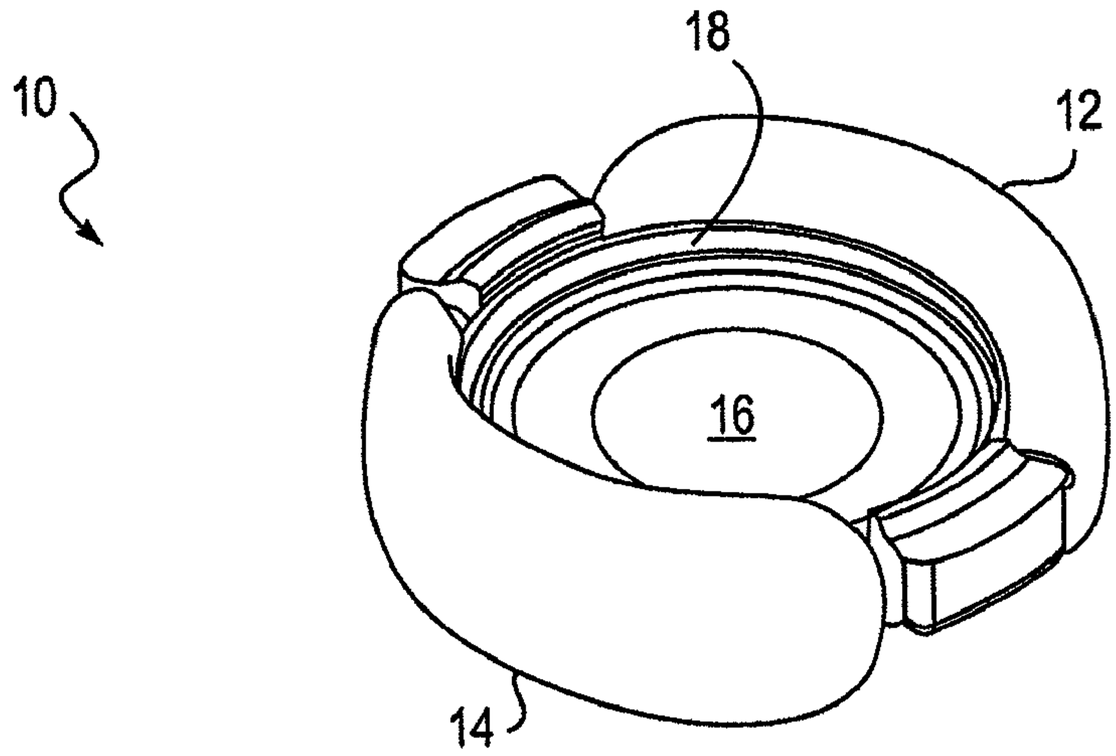

FIG. 3

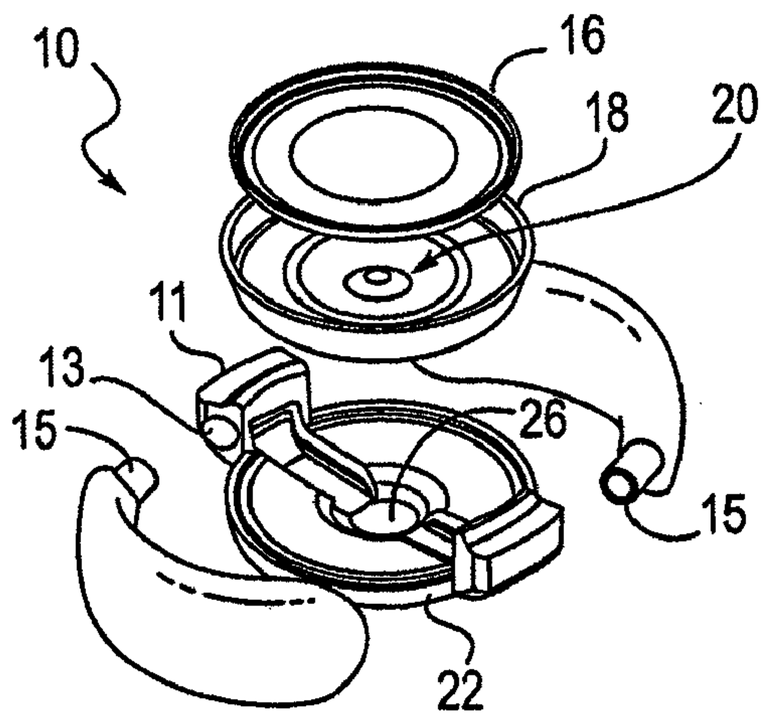

FIG. 4

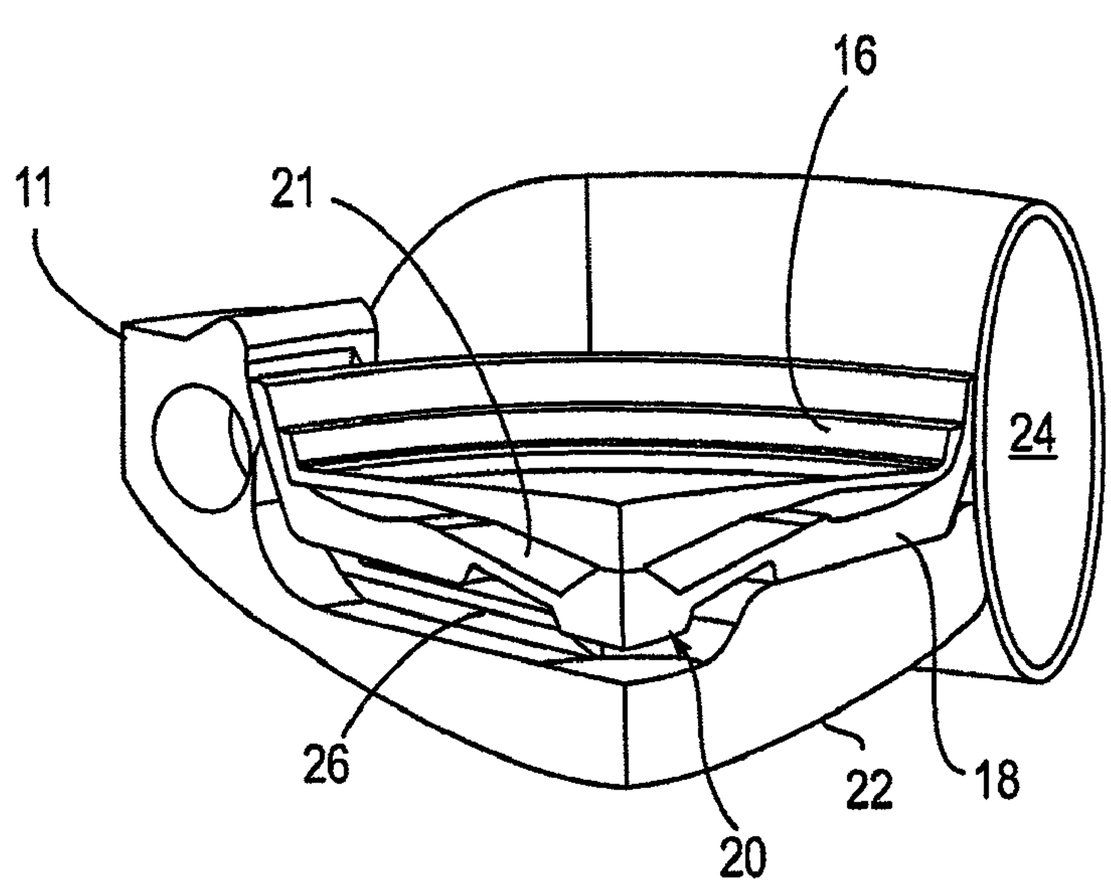

FIG. 5

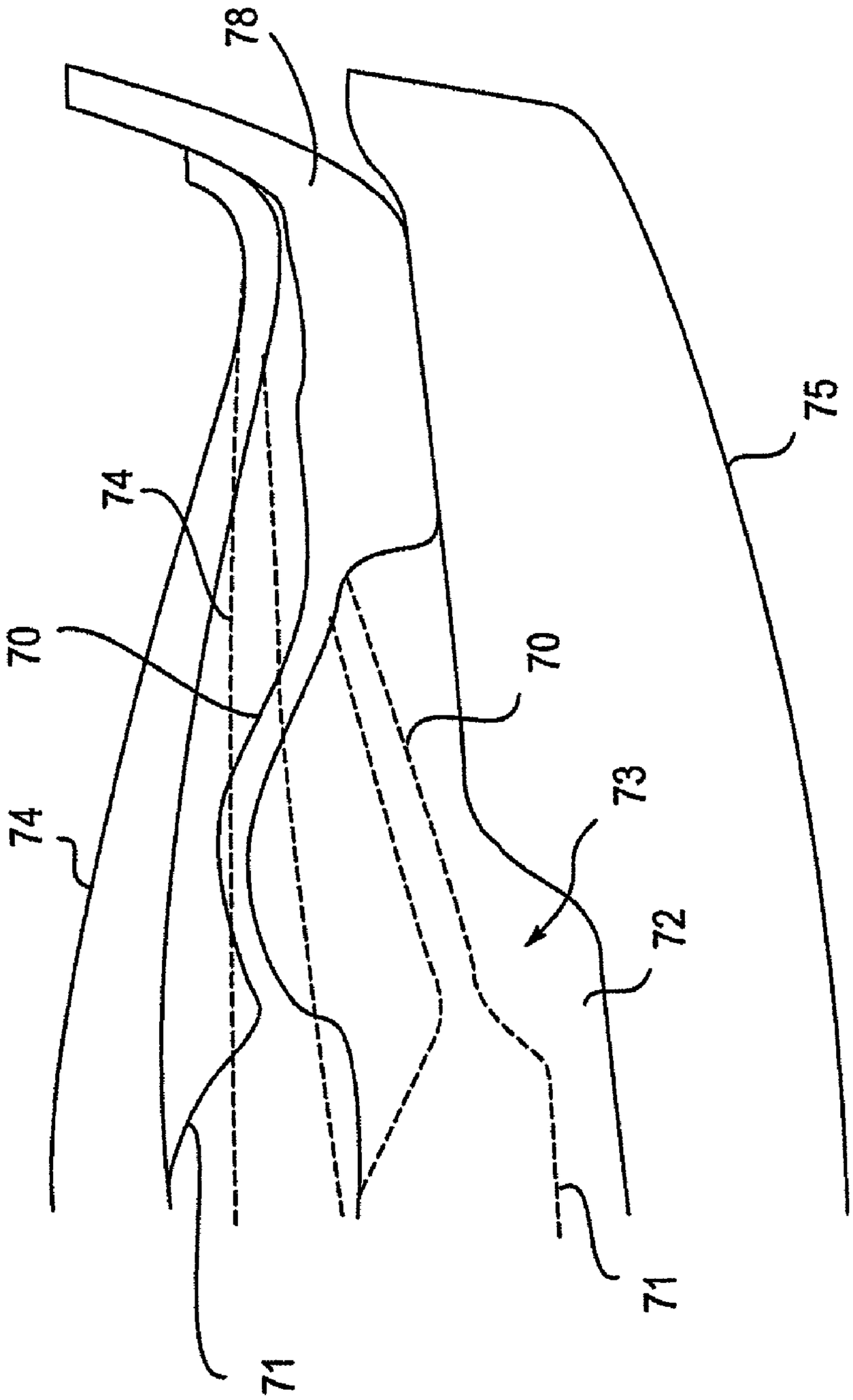

FIG. 6

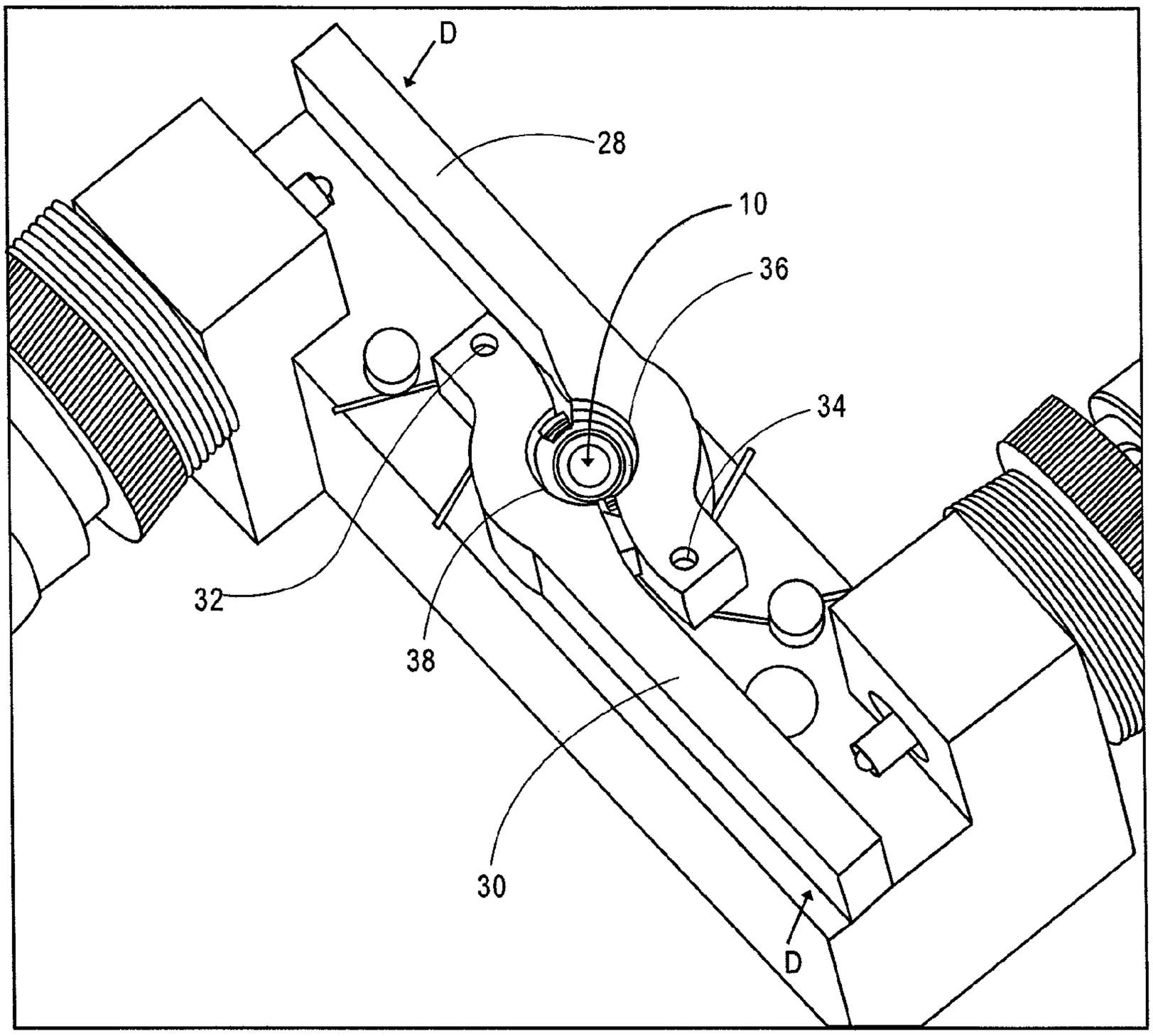

FIG. 7A

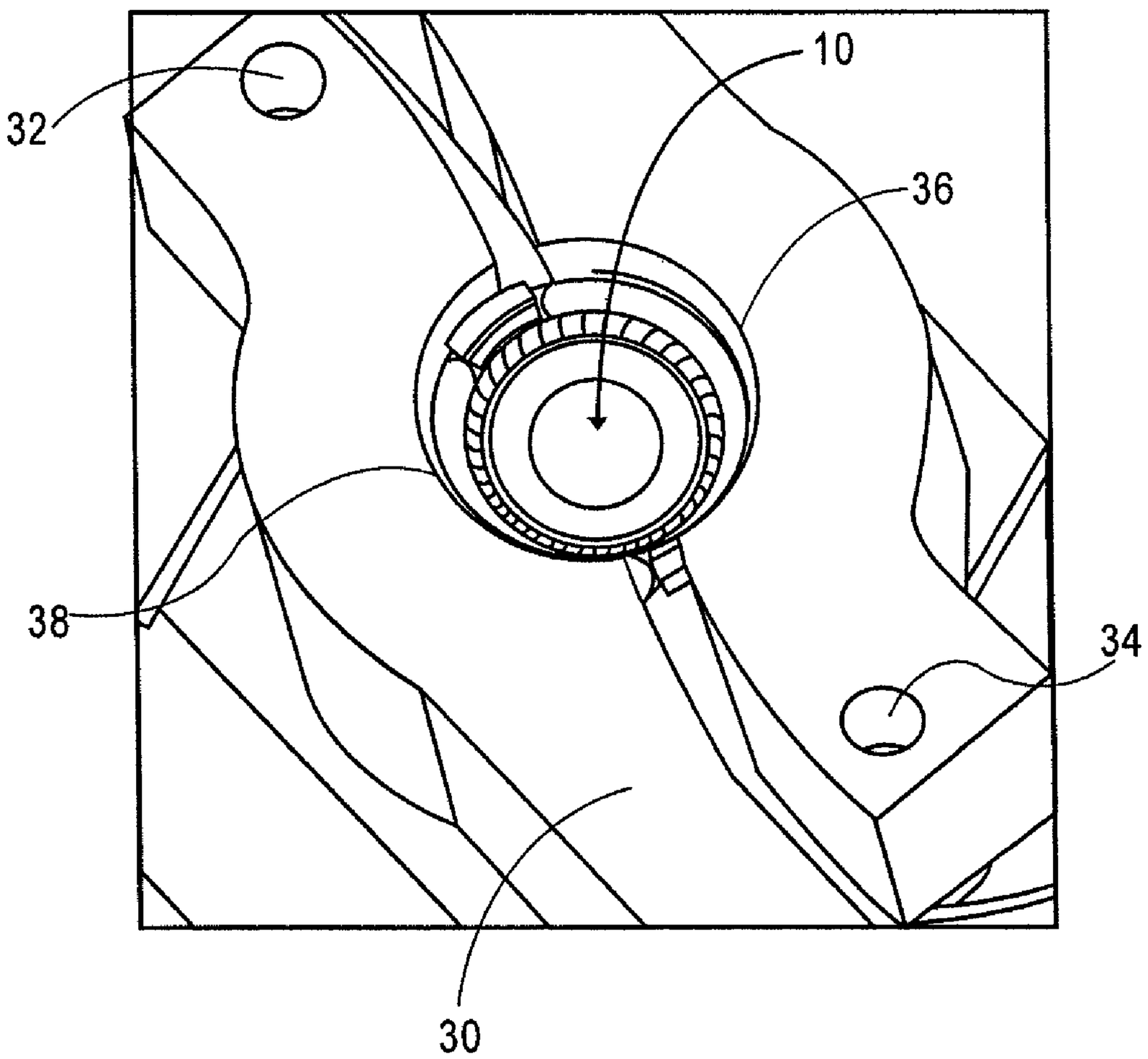

FIG. 7B

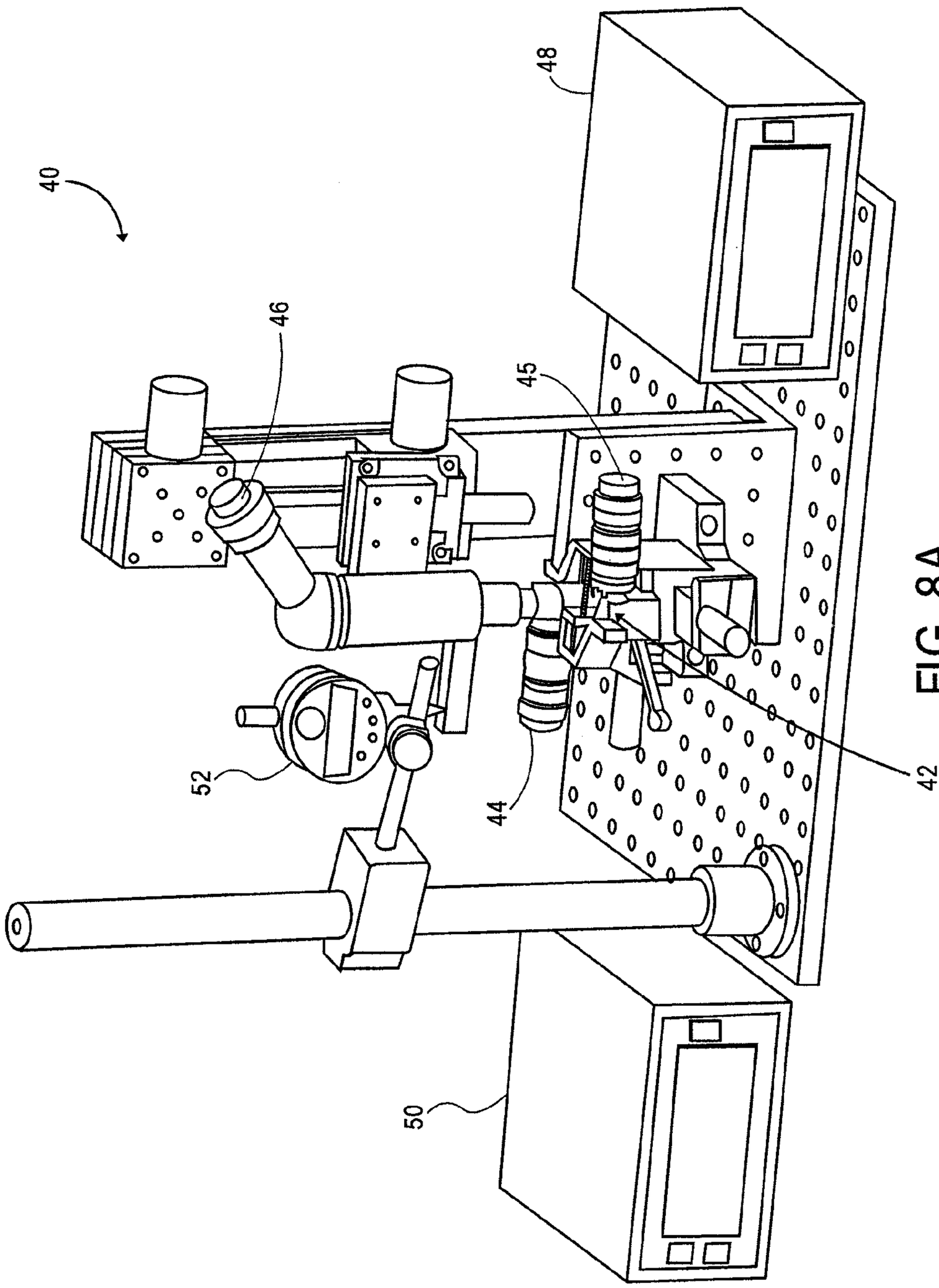

FIG. 8A

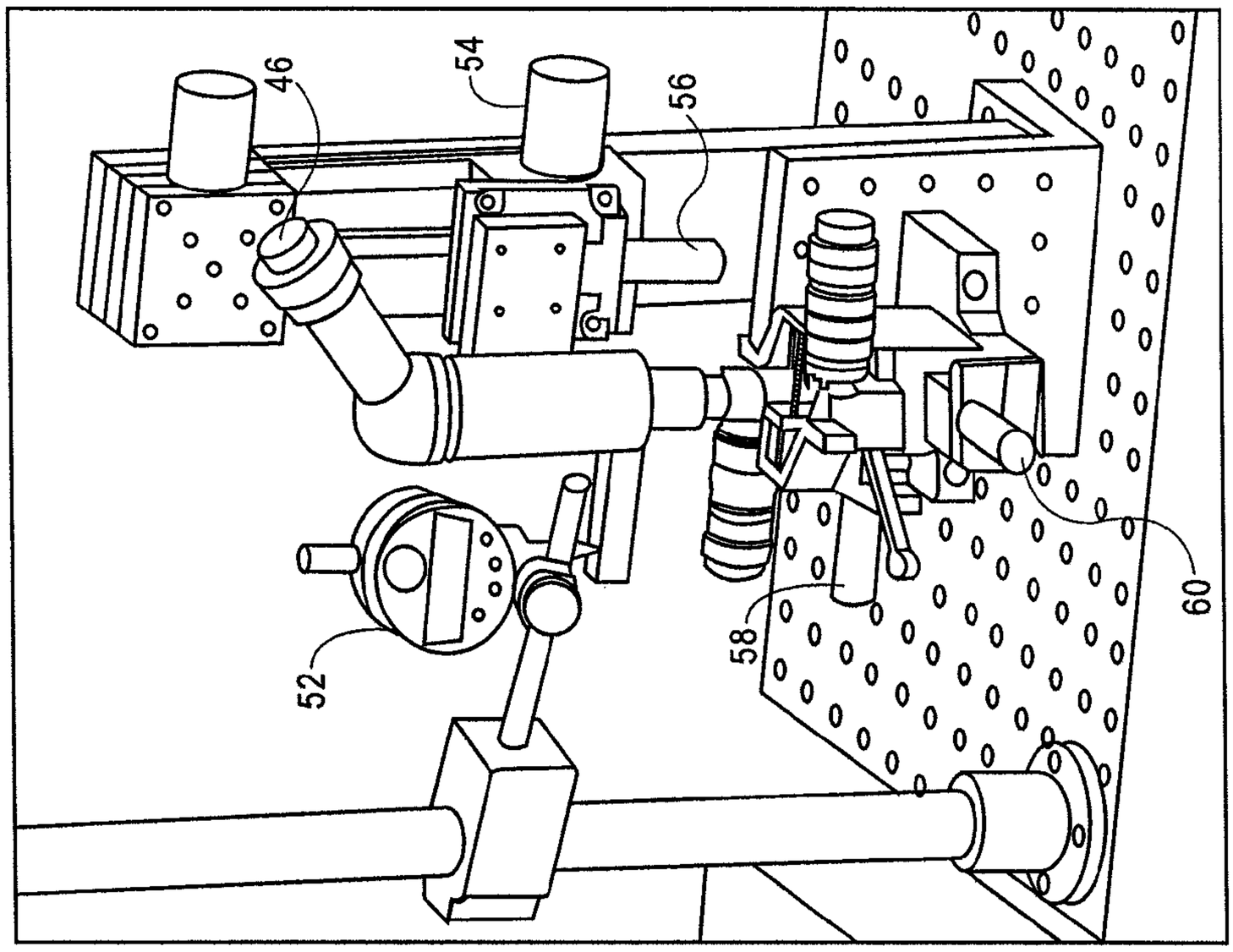

FIG. 8B

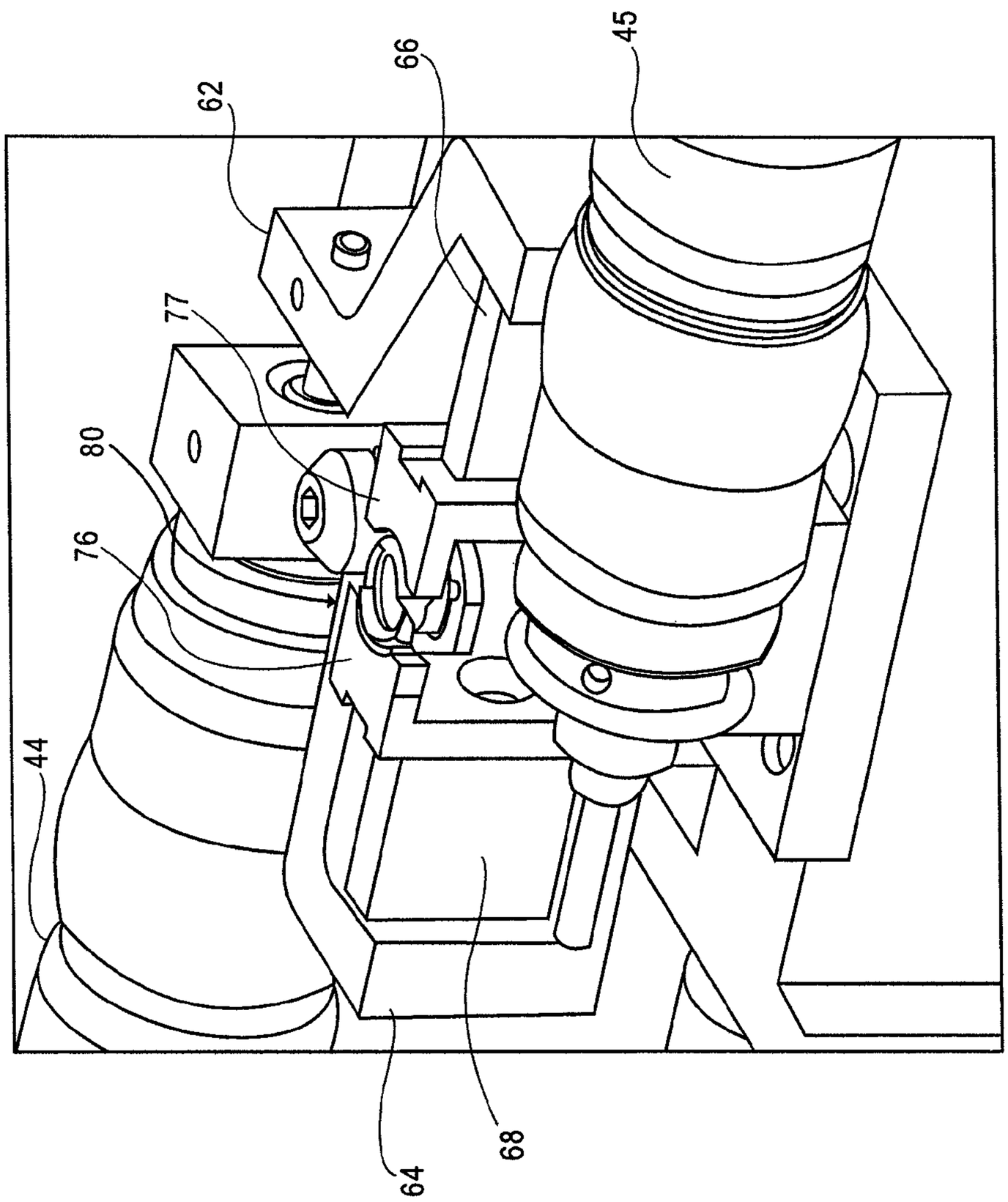

FIG. 8C

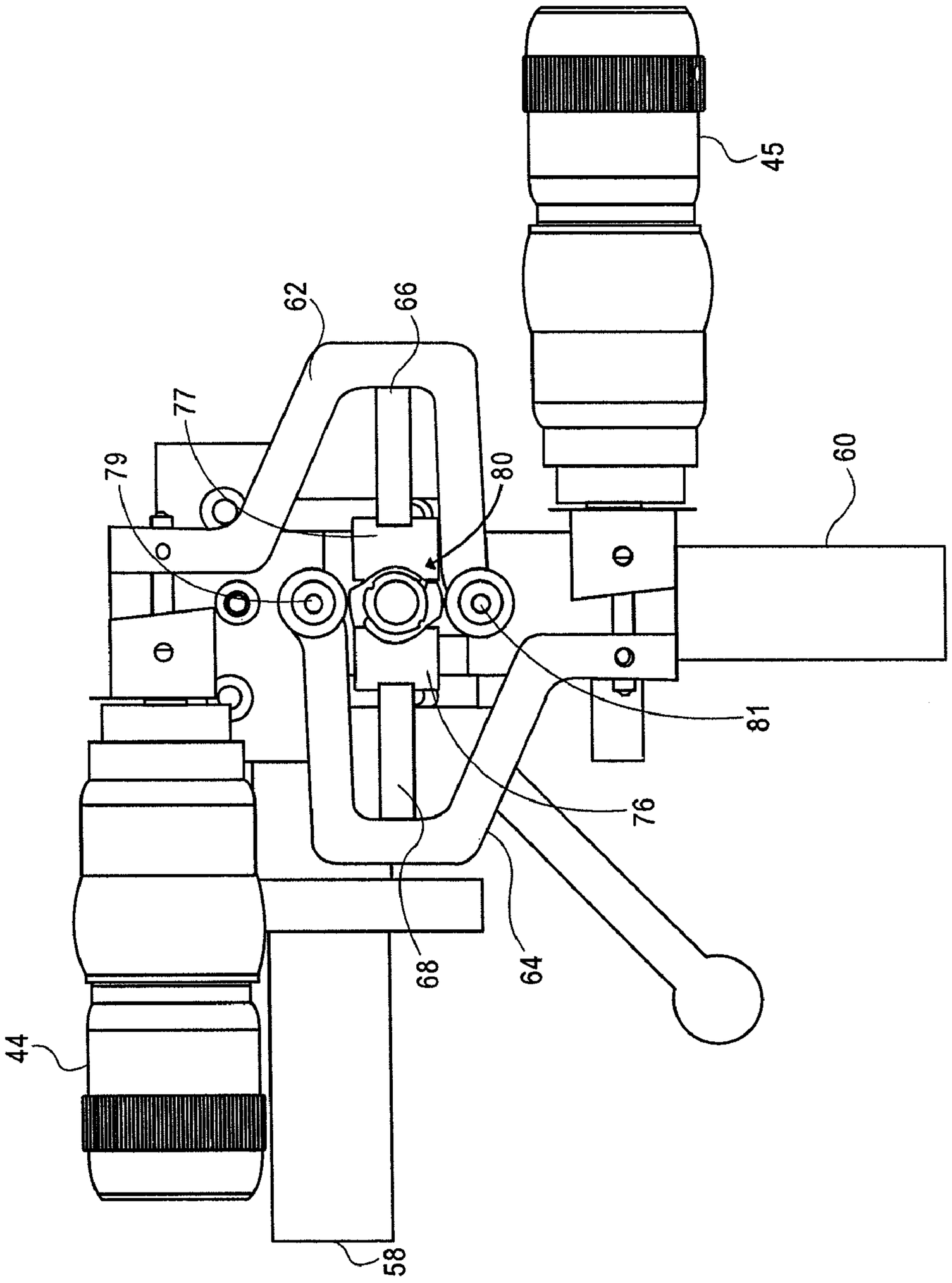

FIG. 8D

SYSTEMS AND METHODS FOR TESTING INTRAOCULAR LENSES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/951,441, filed Jul. 23, 2007, which is hereby incorporated by reference as if fully set forth herein.

BACKGROUND OF THE INVENTION

Cataracts are a major cause of blindness in the world and the most prevalent ocular disease. When the disability from cataracts affects or alters an individual's activities of daily living, surgical lens removal with intraocular lens ("IOL") implantation is the preferred method of treating the functional limitations.

A cataract is any opacity of a patient's lens, whether it is a localized opacity or a diffuse general loss of transparency. To be clinically significant, however, the cataract must cause a significant reduction in visual acuity or a functional impairment. A cataract occurs as a result of aging or secondary to hereditary factors, trauma, inflammation, metabolic or nutritional disorders, or radiation. Age related cataract conditions are the most common.

In treating a cataract, the surgeon removes the crystalline lens matrix from the lens capsule and replaces it with an IOL. The typical IOL provides a selected focal length that allows the patient to have fairly good distance vision. Since the lens can no longer accommodate, however, the patient typically needs glasses for reading.

More specifically, the imaging properties of the human eye are facilitated by several optical interfaces. A healthy youthful human eye has a total power of approximately 59 diopters, with the anterior surface of the cornea (e.g. the exterior surface, including the tear layer) providing about 48 diopters of power, while the posterior surface provides about −4 diopters. The crystalline lens, which is situated posterior of the pupil in a transparent elastic capsule, also referred to herein as "capsular sac," supported by the ciliary muscles via zonules, provides about 15 diopters of power, and also performs the critical function of focusing images upon the retina. This focusing ability, referred to as "accommodation," enables imaging of objects at various distances.

The power of the lens in a youthful eye can be adjusted from 15 diopters to about 29 diopters by adjusting the shape of the lens from a moderately convex shape to a highly convex shape. The mechanism generally accepted to cause this adjustment is that ciliary muscles supporting the capsule (and the lens contained therein) move between a relaxed state (corresponding to the moderately convex shape) and a contracted state (corresponding to the highly convex shape). Because the lens itself is composed of viscous, gelatinous transparent fibers, arranged in an "onion-like" layered structure, forces applied to the capsule by the ciliary muscles via the zonules cause the lens to change shape.

Isolated from the eye, the relaxed capsule and lens take on a more spherical shape. Within the eye, however, the capsule is connected around its circumference by approximately 70 tiny ligament fibers to the ciliary muscles, which in turn are attached to an inner surface of the eyeball. The ciliary muscles that support the lens and capsule therefore are believed to act in a sphincter-muscular mode. Accordingly, when the ciliary muscles are relaxed, the capsule and lens are pulled about the circumference to a larger diameter, thereby flattening the lens, whereas when the ciliary muscles are contracted the lens and capsule relax somewhat and assume a smaller diameter that approaches a more spherical shape.

As noted above, the youthful eye has approximately 14 diopters of accommodation. As a person ages, the lens hardens and becomes less elastic, so that by about age 45-50, accommodation is reduced to about 2 diopters. At a later age the lens may be considered to be non-accommodating, a condition known as "presbyopia". Because the imaging distance is fixed, presbyopia typically entails the need for bifocals to facilitate near and far vision.

Apart from age-related loss of accommodation ability, such loss is innate to the placement of IOLs for the treatment of cataracts. IOLs can be single element lenses made from a suitable polymer material, such as acrylics or silicones. After placement, accommodation is no longer possible, although this ability is typically already lost for persons receiving an IOL. There is significant need to provide for accommodation in IOL products so that IOL recipients will have accommodating ability. In addition, although efforts have been made with accommodating IOLs, there is a need for an accommodating IOL that can restore as much accommodation to the eye as possible.

What is needed is a device to test an accommodative intraocular lens to measure the intraocular lens's accommodative response to a force that is applied to it. It may also be desirable that the device be able to measure the intraocular lens's accommodative response to a simulated external actuation of the lens.

SUMMARY OF THE INVENTION

One aspect of the invention is a method of testing an accommodative response of an intraocular lens. The method includes applying a force to the intraocular lens when the intraocular lens is outside of a lens capsule and measuring an accommodative response of the intraocular lens based on the applied force.

In some embodiments wherein applying a force to the intraocular lens comprises applying a force to a peripheral portion of the intraocular lens.

In some embodiments applying a force to the intraocular lens comprises applying a compressive force to the intraocular lens. Applying a compressive force can comprises applying a radially compressive force to the intraocular lens.

In some embodiments applying a force to the intraocular lens comprises displacing a flowable media within the intraocular lens from a peripheral portion of the intraocular lens to an optic portion of the intraocular lens.

In some embodiments measuring an accommodating response of the intraocular lens comprises measuring the deflection of a surface of the intraocular lens.

In some embodiments measuring the deflection of a surface of the intraocular lens comprises measuring the deflection of an anterior surface of the intraocular lens.

In some embodiments measuring an accommodative response of the intraocular lens comprises optically measuring an accommodative response of the intraocular lens.

In some embodiments the method also includes measuring the force applied to the intraocular lens and relating it to the measured accommodative response.

In some embodiments measuring an accommodative response of the intraocular lens comprises measuring a change of configuration of the lens or a portion of the lens.

One aspect of the invention is a system for measuring an accommodative response of an intraocular lens outside of a lens capsule. The system comprises a force effector adapted to apply a force on an intraocular lens and an accommodative

response measuring element adapted to measure an accommodative response of the intraocular lens based on the force applied by the force effectors.

In some embodiments the force effector is adapted to apply a radially compressive force on the intraocular lens.

In some embodiments the force effector is a first force effector and the system further comprises a second force effector, wherein the first force effector is disposed substantially opposite the second force effector around the periphery of the intraocular lens.

In some embodiments the force effector is a first force effector and the system further comprises a second force effector, wherein the first force effector is adapted to be actuated with a first compression actuator to apply a force to intraocular lens and the second force effector is adapted to be actuated with a second compression actuator to apply a second force to the intraocular lens.

In some embodiments the system further comprises a force measuring element adapted to measure the force applied to the intraocular lens. In some embodiments the force measuring element is a load cell.

In some embodiments the accommodative response measuring element is adapted to measure deflection of a surface of the intraocular lens. The accommodative response measuring element comprises can be a microscope adapted to sense a focus plane on a surface of the intraocular lens.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIGS. **1**, **2**A, and **2**B illustrate the structure and operation of a human eye.

FIGS. **3**-**5** show an exemplary embodiment of an intraocular lens.

FIG. **6** shows a portion of an exemplary intraocular lens in disaccommodative and accommodative configurations.

FIGS. **7**A and **7**B illustrate an exemplary intraocular lens testing device.

FIGS. **8**A-**8**D show an exemplary intraocular lens testing system.

DETAILED DESCRIPTION OF THE INVENTION

The invention relates generally to systems and devices for testing an intraocular lens ("IOL") and in some embodiments systems for testing accommodating IOLs. The devices are adapted to test the intraocular lens outside of the lens capsule. In some embodiments the IOL includes a flowable media (such as a fluid, gelatinous material, etc.) that is moved within the IOL, in response to ciliary muscle movement, to change the power of the IOL.

FIGS. **1**, **2**A and **2**B illustrate the structure and operation of a human eye. Eye **100** includes cornea **1**, iris **2**, ciliary muscles **3**, ligament fibers or zonules **4**, capsule **5**, lens **6** and retina **7**. Natural lens **6** is composed of viscous, gelatinous transparent fibers, arranged in an "onion-like" layered structure, and is disposed in transparent elastic capsule **5**. Capsule **5** is joined by zonules **4** around its circumference to ciliary muscles **3**, which are in turn attached to the inner surface of eye **0**. Vitreous **8** is a highly viscous, transparent fluid that fills the center of eye **100**.

Isolated from the eye, the relaxed capsule and lens take on a convex shape. However, when suspended within the eye by zonules **4**, capsule **5** moves between a moderately convex shape (when the ciliary muscles are relaxed) and a highly convex shape (when the ciliary muscles are contracted). As shown in FIG. **2**A, when ciliary muscles **3** relax, capsule **5** and lens **6** are pulled about the circumference, thereby flattening the lens. As shown in FIG. **2**B, when ciliary muscles **3** contract, capsule **5** and lens **6** relax and become thicker. This allows the lens and capsule to assume a more convex shape, thus increasing the diopter power of the lens.

Additionally, various natural mechanisms affect the design requirements of the present invention. For example, during accommodation the pupil naturally stops down (i.e., reduces in diameter) which reduces the area of the natural lens that transmits light. In addition, the eye will experience the Stiles-Crawford Effect which also reduces the effective area of the natural lens. In particular, the brightness of light rays incident on cones in the eye is dependent on the angle at which those rays are incident on the cones. In particular, light rays that strike the cones perpendicular to their surface appear brighter than those that do not. As a result, the light rays passing through the periphery of the lens are less significant for proper vision.

FIGS. **3**-**5** show a first embodiment of accommodating IOL **10** that can be tested using the system described herein. IOL **10** includes a peripheral non-optic portion comprising haptics **12** and **14**. The IOL also includes an optic portion including anterior lens element **16**, intermediate layer **18** which comprises actuator **20**, and substrate, or posterior element, **22**. Anterior element **16** is bonded to intermediate layer **18** at its periphery. In some embodiments the anterior element may also be bonded to actuator **20**. The intermediate layer is also bonded to posterior element **22**. The inner surface of haptics **12** and **14** define interior volumes **24** which are in fluid communication with active channel **26** defined by posterior element **22** and intermediate layer **18**. As shown, actuator **20** is integral with intermediate layer **18**. Posterior element **22** is molded with buttresses **11** which include a buttress bore **13** therethrough. The haptics have a haptic attachment element **15** (which can be stiff or flexible) which is sized and shaped to fit within buttress bore **13**. An adhesive layer can be applied to the outer surfaces of the haptic attachment elements and/or the inner surface of the buttress bore to facilitate attachment of the haptics to the optic portion. The IOL contains a flowable media within the haptics and the active channel. The IOL also includes passive chamber **21** that is defined by the anterior element and the intermediate layer. The passive chamber contains a second flowable media (e.g., a fluid, elastomer, etc.), which may be the same as the fluid within the haptics and active channel, or it may be a different flowable media. The active channel and the passive chamber are not in fluid communication.

Deformation of haptics **12** and **14** in response to contraction of ciliary muscles movement transfers the flowable media (such as a fluid) between interior volume **24** and active channel **26**. When the flowable media is transferred into the active channel from the haptics, the pressure in the active channel increases, causing actuator **20** to deflect in the ante-

rior direction. This causes anterior element **16** to deflect in the anterior direction, increasing the IOL power in this accommodated configuration.

FIG. **6** is a cross sectional view of a portion of an exemplary IOL showing the IOL in a disaccommodated state (dashed lines) and an accommodated state (solid lines). The IOL includes anterior element **74**, intermediate layer **78** which includes actuator **73**, and posterior element **75**. Actuator **73** is comprised of deflection element **71** and bellows **70**. When the pressure is increased in active channel **72**, bellows **70** change configuration from the generally conical shape of the disaccommodated state to a curvilinear configuration of the accommodated state. Deflection element **71** is forced in the anterior direction due to the increase in pressure. This causes anterior element **74** to deflect in the anterior direction as well, steepening the curvature of the anterior element and thereby increasing the power of the lens.

Additional exemplary IOLs that can be tested using the systems described herein are described in U.S. Provisional Application No. 60/433,046, filed Dec. 12, 2002; U.S. Pat. Nos. 7,122,053; 7,261,737; 7,247,168; and 7,217,288; U.S. patent application Ser. No. 11/642,388, filed Dec. 19, 2006, and U.S. patent application Ser. No. 11/646,913, filed Dec. 27, 2006, the disclosures of which are hereby incorporated herein by reference.

The systems described herein can also be used to test any other suitable accommodating IOL which is adapted to change power in response to ciliary muscle movement. For example, an accommodating IOL comprised entirely of a polymeric material can be tested in the systems described herein.

The systems and devices described herein are generally used to test and analyze an IOL's accommodative response to a force applied to the lens. The accommodative response can be any detectable change in the IOL. Exemplary detectable responses include, without limitation, a change in dimension of the lens or a portion of the lens, a change in configuration of the lens or a portion of the lens, a change in shape from a first shape to a second shape, etc.

The change can be measured by almost any means, including optical, mechanical, electrical, etc. In some cases the change may also be detected by the human eye. This may not, however, be as reliable.

The systems and devices can also be used generally to test the strength of an IOL. That is, in response to a force applied to the IOL, the devices can test how well the IOL responds to those forces, and at what point the IOL begins to, for example, fatigue, fracture, etc.

The force can be applied to any portion of the IOL, but in some embodiments it is applied to a peripheral portion of the an IOL that is adapted to contact the lens capsule when implanted in the eye. The direction of the force can be applied in almost any direction, but in some embodiments the force is applied radially inward and is applied to a peripheral portion of the IOL.

FIGS. **7**A and **7**B show an exemplary embodiment of a testing device used to test and analyze the radial compression and/or strength of IOL **10**, which is also shown in FIGS. **3**-**5**. The testing device includes arms **28** and **30** which pivot about pivot points **34** and **32**, respectively. From the position shown in FIG. **7**A, the arms are actuated in a counter-clockwise direction "D" which decreases the space between the two semi-circular portions **36** and **38** of arms **28** and **30**, thus engaging haptics **12** and **14** and radially compressing the lens. The testing device can be used to measure and relate a compressive force applied to the haptics to the responsive change in the anterior element of the IOL. In reference to FIG. **6**, the compressive force is measured and related to the change in the height of anterior element along a center point of the optic portion. That is, the change in height is the distance from the anterior surface of anterior element **74** in the disaccommodated state (dashed lines) to the anterior surface of anterior element **74** in the accommodated state (solid lines), along the center of the optic portion.

The change can be measured in almost way. For example, at substantially the center of the lens the thickness of the assembly can be measured from the posterior side of the posterior lens element to the anterior side of the anterior lens element. Alternatively, the thickness can be assessed by measuring the central height of the lens relative to a reference measurement such an outer edge of the optic.

As the arms are rotated, they compress the lens in a radial direction, causing a decrease in lens diameter and an increase in optic portion height. The height is increased as fluid is squeezed from the haptics and into the optic portion, causing anterior deflection of the anterior element of the lens.

FIGS. **8**A-**8**D illustrate an exemplary embodiment of radial compression system **40**. System **40** includes IOL placement location **42** (shown in more detail in FIGS. **8**C and **8**D), radial compression actuators **44** and **45**, microscope **46**, force readouts **48** and **50**, and lens surface indicator **52**. As shown in FIG. **8**B, the system also includes microscope course z-axis adjustor **56** and microscope fine z-axis adjustor **54**. System **40** also includes X and Y positioners **58** and **60** for centering IOL **80** in IOL placement location **42**. As shown in more detail in the perspective view and the top view of FIG. **8**C and FIG. **8**D, respectively, the system includes radial compression actuators **44** and **45** which are coupled to and adapted to actuate arms **62** and **64**, respectively (In FIG. **8**C, a portion of arm **64** is not shown for clarity). Arms **62** and **64** pivot around pivot **81** and **79**, respectively, when actuated by radial compression actuators **44** and **45**. Arms **62** and **64** are coupled to load cells **66** and **68**, respectively. Load cells **66** and **68** are coupled to lens compression effectors **77** and **76**, respectively. The compression effectors as shown are disposed substantially opposite each other around the periphery of the intraocular lens.

When the radial compression actuators actuate the arms, the lens compression effectors radially compress IOL **80** in the IOL placement location.

In use, IOL **80** is placed in IOL placement location **42** and X and Y positioners **58** and **60** are adjusted to center the IOL. Radial compression actuators **44** and **45** are then actuated (manually or automatically) to cause effectors **77** and **81** to radially compress IOL **80**. In some embodiments the radial compression actuators are adjusted symmetrically during a test cycle. A surface of the effectors adjacent the IOL is curved to correspond to the curve of the periphery of the IOL.

The radial compression forces can be adapted to mimic forces that will be applied to the IOL (and particularly the forces applied to the periphery of the IOL) by the lens capsule in order to measure how the IOL responds to in-the-capsule conditions.

The load cells of the system can detect the amount of force (e.g., compressive force) applied to the IOL at each of the effectors. Force readouts **48** and **50** are adapted to display the amount of force applied to the IOL. The raw or analyzed data can of course by stored on any kind of computer system. As the amount of force that is applied the IOL is adjusted, a user actuates (or they are automatically actuated) the course and fine microscope z-position adjustors so microscope **46** senses the focus plane on the top (e.g., anterior) surface of the IOL. The microscope can focus on the top surface of the IOL and therefore detect the highest point on the anterior surface of the IOL for any given amount of force applied by the effectors. In

this way the systems knows, for a given amount of force(s) applied to the IOL, how much the anterior element is deflecting. Lens surface indicator **52** is adapted to give a readout of the location of the lens surface. Raw or analyzed data can of course be stored in a computer system.

The testing device can be used to test alternative IOL designs or it can be used to test an IOL to make sure it is within tolerances.

Some intraocular lenses are adapted to be adjusted after being implanted in the lens capsule. Exemplary IOLs that can be adjusted post-implant are described in co-pending U.S. application Ser. No. 12/178,304, filed Jul. 23, 2008, the disclosure of which is incorporated by reference herein. For example, some IOLs can be actuated by an external energy source to alter the volume and/or pressure within the IOL, or to displace a flowable media from a first portion of the IOL to a second portion. The testing systems described herein can be adapted to test the IOL's accommodative response based on the application of energy from an external energy source.

For example, an IOL adapted to be adjusted post-implant can be placed in the IOL placement location and the effectors can be actuated (via the radial compression actuators) to cause the effectors to contact (i.e., engage) the IOL. The effectors can be further actuated to compress the peripheral haptics to mimic, for example, a capsule that has contracted, or shrunk, around the peripheral portion of the IOL after the IOL has been implanted in the capsule (which can be a natural response to an IOL implantation procedure). The microscope can be used to sense a first focus plane with the haptics in the compressed configuration. The IOL is then actuated with an external energy source (e.g., a laser) to actuate a portion of the lens to adjust the pressure and/or volume of the IOL, to displace fluid from a first portion of the lens to a second portion of the lens, or any other post-implant adjustment that may be needed to be made. The microscope is then used to sense the focus plane after the IOL has been adjusted. In this manner in can be determined how much the lens has disaccommodated or accommodated in response to the simulated post-implant adjustment.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method of testing an accommodative response of an accommodating intraocular lens, comprising:

applying a force to an accommodating intraocular lens when the accommodating intraocular lens is outside of a lens capsule; and

measuring an accommodative response of the accommodating intraocular lens to the applied force, wherein applying a force to the accommodating intraocular lens comprises applying a compressive force to the accommodating intraocular lens.

2. The method of claim **1** wherein applying a force to the accommodating intraocular lens comprises applying a force to a peripheral portion of the accommodating intraocular lens.

3. The method of claim **1** wherein applying a compressive force comprises applying a radially compressive force to the accommodating intraocular lens.

4. The method of claim **1** wherein applying a force to the accommodating intraocular lens comprises displacing a flowable media within the accommodating intraocular lens from a peripheral portion of the accommodating intraocular lens to an optic portion of the accommodating intraocular lens.

5. The method of claim **1** wherein measuring an accommodating response of the accommodating intraocular lens comprises measuring the deflection of a surface of the accommodating intraocular lens.

6. The method of claim **1** wherein measuring the deflection of a surface of the accommodating intraocular lens comprises measuring the deflection of an anterior surface of the accommodating intraocular lens.

7. The method of claim **1** wherein measuring an accommodative response of the accommodating intraocular lens comprises optically measuring an accommodative response of the accommodating intraocular lens.

8. The method of claim **1** further comprising measuring the force applied to the accommodating intraocular lens and relating it to the measured accommodative response.

9. The method of claim **1** wherein measuring an accommodative response of the accommodating intraocular lens comprises measuring a change of configuration of the lens or a portion of the lens.

10. The method of claim **1** wherein measuring an accommodative response of the accommodating intraocular lens to the applied force comprises measuring an accommodative response of an optic portion of the accommodating intraocular lens to the applied force.

11. The method of claim **1** wherein applying a force to the accommodating intraocular lens simulates a force applied to the accommodating intraocular lens from a native capsular bag.

12. The method of claim **1** wherein measuring an accommodative response comprises measuring a change in optical power of the accommodating intraocular lens in response to the applied force.

13. A system for measuring an accommodative response of an accommodating intraocular lens outside of a lens capsule, comprising:

a force effector adapted to apply a compressive force on an accommodating intraocular lens; and

an accommodative response measuring element adapted to measure an accommodative response of the accommodating intraocular lens to the compressive force applied by the force effector.

14. The system of claim **13** wherein the force effector is adapted to apply a radially compressive force on the accommodating intraocular lens.

15. The system of claim **13** wherein the force effector is a first force effector and the system further comprises a second force effector, wherein the first force effector is disposed substantially opposite the second force effector around the periphery of the accommodating intraocular lens.

16. The system of claim **13** wherein the force effector is a first force effector and the system further comprises a second force effector, wherein the first force effector is adapted to be actuated with a first compression actuator to apply a force to the accommodating intraocular lens and the second force effector is adapted to be actuated with a second compression actuator to apply a second force to the accommodating intraocular lens.

17. The system of claim 13 wherein the system further comprises a force measuring element adapted to measure the force applied to the accommodating intraocular lens.

18. The system of claim 17 wherein the force measuring element is a load cell.

19. The system of claim 13 wherein the accommodative response measuring element is adapted to measure deflection of a surface of the accommodating intraocular lens.

20. The system of claim 19 wherein the accommodative response measuring element comprises a microscope adapted to sense a focus plane on a surface of the accommodating intraocular lens.

21. The system of claim 13 further comprising the accommodating intraocular lens.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,314,927 B2
APPLICATION NO. : 12/178454
DATED : November 20, 2012
INVENTOR(S) : Choi et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 352 days.

Signed and Sealed this
Eighteenth Day of November, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office